Art Unit 3763

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: Williams, Catherine Serke

Application No.: 10/773,538

Filing Date: February 6, 2004

Title: Needle Guard

Customer No.: 27162

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the Final Rejection dated May 22, 2006 of claims 2 and 3.

A check in the amount of $250.00 is submitted herewith. Should any additional fees be required, please charge such to Deposit Account 03-0678.

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REAL PARTY IN INTEREST

The real party in interest is Michael J. Vaillancourt.

RELATED APPEALS AND INTERFERENCES

There are no related Appeals or Interferences.

STATUS OF CLAIMS

Claim 1 has been canceled.

Claims 2 and 3 have been rejected.

Claim 4 to 12 have been objected to as dependent upon a rejected claim but would be allowable if rewritten in independent form.

STATUS OF AMENDMENTS

All amendments have been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

This invention relates to a needle guard that encloses a sharpened needle edge either during a procedure for inserting a catheter or the like in a patient or upon removal of a sharpened needle after use from a patient. (page 1, lines 3 to 6). The needle guard can be moved from a first position (Fig. 27) where the sharpened edge of the needle is exposed for use to a second position (Fig. 24) where the tip of the sharpened needle is substantially enclosed. (page 2, lines 16 to 18).

Claim 2

Independent claim 2 is directed to the combination of a hub (19; Fig.24), a needle (312; Fig.24; Preliminary Amendment of page 10, line 3 et seq) secured to and extending from the hub (19), a needle housing (101; Fig.27; Preliminary Amendment of page 10, line 3 et seq) removably mounted on the hub (19) and a polyester film

strip (110; Figs. 24 and 27; Preliminary Amendment of page 10, line 3 et seq) secured to and between the hub (19) and the housing (101).

In addition, the needle housing (101) has an aperture (105; Fig.24) at one end with the needle passing therethrough and the polyester film strip (110) has a series of longitudinally spaced apart apertures (111; Fig. 23) receiving the needle (312) therein and being disposed in corrugated relation between the hub (19) and the housing (101). In response to a withdrawal movement of the needle (312) relative to the housing (101) [during removal of the needle from a patient], the needle (312) moves into the housing (101) and into abutment with the housing (101) while the strip (110) is stretched between the hub (19) and the housing (101) to retain the housing (101) connected to the hub (19) under a biasing force.

Claim 3

Claim 3 depends from claim 2 and further requires a washer (102; Figs. 20 and 24) in the housing (101) with flaps (241; Fig.20) to define an aperture for passage of the needle (12) therethrough.

In response to withdrawal of the needle (12) through the aperture (105) in the housing (101), the flaps (241) flex inwardly to block a return passage of the needle (12) through the aperture (105; Preliminary Amendment of page 10, line 3 et seq).

Grounds of Rejection to be reviewed on Appeal

I. Whether Claims 2 and 3 are unpatentable over Wemmert (US 6,234,999) under 35 USC 103(a).

ARGUMENT

Wemmert describes a catheter and introducer needle assembly 10 (see Fig. 2).

The catheter assembly 20 includes a catheter 21 and a catheter hub 24 affixed to the catheter 21. (column 4, lines 13 – 15).

The introducer needle assembly 30 includes a needle 31, a hub 34 connected to the needle 31, a needle shield 40 that receives the catheter assembly 20 and a tether 44. (see Fig. 2).

A transverse barrier 49 (see Fig. 8) is located in the needle shield 40 to act as a barrier to re-exposure of the sharp tip of the introducer needle 31 after it has been withdrawn into the main body portion 41 of the shield 40. This barrier 49 is formed with two lips 49a in the configuration of a duckbill. After placement of the catheter 21 into a patient's blood vessel, the lips 49a ride along the introducer needle 31 when the introducer needle 31 is being withdrawn from the catheter 21. (column 5, lines 46 to 49). Once the tip of the introducer needle 31 is withdrawn to a position proximal of the lips 49a, the resilient nature of the lips 49a causes them to return to a position transverse to the introducer needle 31. (column 5, lines 49 to 52). The configuration of the lips 49a prevents reexposure of the tip that could occur if the introducer needle 31 were thereafter moved distally with respect to the needle shield 40. (column 5, lines 52 to 56; Fig.8).

As the needle hub 34 is moved proximally with respect to catheter hub 24, the needle shield 40 remains adjacent to the catheter hub 24. (column 5, lines 63 to 66 and Fig. 2). During this time, the sharp tip of the needle 31 moves into the shield 40 and

past the barrier 49. Any additional proximal movement of the needle hub 34 will separate the needle shield 40 from the catheter hub 24. (column 6, lines 1 to 7).

The tether 44 has a length that maintains the sharp distal tip of the needle 31 in the main body portion 41 of the needle shield 40 when the tether 44 is fully extended. (column 5, line 66 to column 6, line 1). The tether 44 can be made of any relatively stiff yet flexible material with polyethylene terephthalate as the preferred material. One benefit of using this material is that it is relatively stiff so that when it is folded into a pleated or an accordion-like configuration, it provides a slight biasing force to help maintain tether 44 in the completely extended position. (column 6, lines 38 to 44).

Wemmert does not meet the claim limitations of claim 2

Claim 2 requires that, in response to a withdrawal movement of the needle relative to the housing, "said strip is stretched between said hub and said housing to retain said housing connected to said hub under a biasing force".

Wemment does not stretch the tether 44. Instead, the tether 44 is made of a relatively stiff material so that when it is folded, it provides a slight biasing force to help maintain tether 44 in the completely extended position. That is to say, the tether 44 is biased outwardly from the folded position of Fig. 7 to the extended position of Fig. 2. Thus, the tether is under an expanding force in the Fig. 2 position and not under a contracting force as it would be if the tether 44 were stretched as required by claim 2.

As viewed in Fig. 2 of Wemmert, the needle hub 24 is pushed away from the shield 40 by the tether 44 and is not drawn toward the shield 40 as it would be if the tether 44 were stretched as required by claim 2.

Note also that Wemmert teaches at column 6, lines 63 et seq that the combination of the material of the tether 44, the pleated configuration of the tether 44 and the specific connection of the distal pleat 44c to the main body portion 41 of the shield 40 causes the longitudinal axis of the main body portion 41 to form an oblique angle with respect to the needle 31 when the tether 44 is fully extended to ensure that the needle 31 remains trapped if the needle 31 were to be moved distally. This is further evidentiary that the needle hub 24 of Wemmert is pushed away from the shield 40 by the tether 44 and is not drawn toward the shield 40 as it would be if the tether 44 were stretched as required by claim 2.

In view of the above, a rejection of claim 2 as being unpatentable over Wemmert is not warranted pursuant to the provisions of 35 USC 103.

Wemmert does not meet the claim limitations of claim 3

Claim 3 depends from claim 2 and further requires "a washer mounted in said housing and having flaps to define an aperture for passage of said needle. . . ". The Examiner alleges that the transverse barrier 49 of Wemmert is a washer.

As can be seen in Fig. 5 of Wemmert, the transverse barrier 49 is in the form of a tube. The term "washer" is described in Webster's New Collegiate Dictionary as follows:

> washer: 2:a flat thin ring or a perforated plate used in joints or assemblies to ensure tightness, prevent leakage, or relieve friction.

The plain meaning of the term "washer" is not met by the tube 49 of Wemmert.

Further, Wemmert describes the barrier 49 as being formed with two lips 49a (see Fig. 8) in the configuration of a duckbill. Such a barrier is not a "washer" as claimed.

In view of the above, a rejection of claim 3 as being unpatentable over Wemmert is not warranted pursuant to the provisions of 35 USC 103.

SUMMARY

For the reasons set forth above, the Final Rejection of claims 2 and 3 should be reversed.

The application is believed to be in condition for allowance and such is respectfully requested.

FIRST CLASS CERTIFICATE

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Respectfully submitted,

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APPENDIX

2. In combination,

a hub;

a needle secured to and extending from said hub;

a needle housing removably mounted on said hub, said needle housing having an aperture at one end with said needle passing therethrough; and

a polyester film strip secured to and between said hub and said housing, said strip having a series of longitudinally spaced apart apertures receiving said needle therein and being disposed in corrugated relation between said hub and said housing whereby in response to a withdrawal movement of said needle relative to said housing, said needle moves into said housing and into abutment with said housing while said strip is stretched between said hub and said housing to retain said housing connected to said hub under a biasing force.

3. The combination as set forth in claim 2 further comprising a washer mounted in said housing and having flaps to define an aperture for passage of said needle therethrough whereby in response to withdrawal of said needle through said aperture said flaps flex inwardly to block a return passage of said needle through said aperture.

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